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EXAMINER	
SCHLAPKOHL, WALTER	

ART UNIT	PAPER NUMBER
1636	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,575	MORRIS ET AL.	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-66* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, drawn to **one** isolated nucleic acid selected from the group consisting of SEQ ID NOs: 7, 13, 15, 17…1736, 1738 and 1740, or its complement, a vector comprising said isolated nucleic acid and a host cell comprising said vector, classified in class 536, subclass 23.1.

II. Claims 13-15 and 45-48, drawn to a microarray and an electronic library comprising **one or one combination** of probes selected from the group consisting of SEQ ID NOs: 7, 13, 15, 17…1736, 1738 and 1740; and polynucleotides selected from the group of those which hybridize to SEQ ID NOs: 6, 12, 24, 38…1711, 1719 and 1735 and SEQ ID NOs: 7, 13, 15, 17…1736, 1738 and 1740, classified in class 435, subclass 287.2.

III. Claims 16-21, drawn to **one** isolated polypeptide selected from the group consisting of SEQ ID NOS: 8, 14, 16, 18…1737, 1739 and 1741 and those encoded by SEQ ID NOs: 6, 12, 24, 38…171, 1719 and 1735, classified in class 530, subclass 350.

IV. Claims 22-41, drawn to an antibody and a kit comprising an antibody which binds to **one** isolated peptide selected from the group consisting of SEQ ID NOs: 8, 14, 16, 18…1737, 1739 and 1741 and SEQ ID NOS: 6, 12, 24, 38…1711, 1719 and 1735, classified in class 424, subclass 130.1.

V. Claim 42, drawn to a method of detecting the presence or absence of cancer cells comprising contacting cells from an individual with an antibody which binds to **one** isolated peptide selected from the group consisting of SEQ ID NOs: 8, 14, 16, 18…1737, 1739 and 1741 and SEQ ID NOS: 6, 12, 24, 38…1711, 1719 and 1735, and detecting a complex of said CAP and the antibody, classified in class 435, subclass 7.1.

VI. Claims 43-44 and 62-63, drawn to a method for inhibiting growth of cancer cells in an individual comprising administering of an effective amount of a pharmaceutical composition comprising an antibody which binds to **one** isolated peptide selected from the group consisting of SEQ ID NOs: 8, 14, 16, 18…1737, 1739 and 1741 and SEQ ID NOS: 6, 12, 24…1711, 1719 and 1735, classified in class 424, subclass 130.1.

VII. Claim 49, drawn to an electronic library comprising **one or one combination** of polypeptides selected from the group consisting of SEQ ID NOs: 8, 14, 16…1737, 1739 and 1741, classified in class 422, subclass 61.

VIII. Claims 50-53, drawn to a method of screening for anticancer activity comprising providing a cell that expresses a cancer associated gene encoded by **one or one combination** of nucleic acid sequences selected from the group consisting of the SEQ ID NOS: 6, 12, 24, 28…1711, 1719 and 1735 and SEQ ID NOs: 7, 13, 15…1736, 1738 and 1740; contacting a tissue sample derived from a cancer cell with an anticancer drug candidate; and monitoring an effect of the anticancer drug candidate on expression of the encoded polynucleotide, classified in class 435, subclass 6.

IX. Claims 54-55, drawn to a method for detecting cancer associated with the presence of a polypeptide in a test cell sample comprising the step of detecting a level of expression of **one or one combination** of polypeptides selected from the group consisting of SEQ ID NOs: 8, 14, 16…1737, 1739 and 1741 or a fragment thereof, classified in class 435, subclass 7.1.

X. Claim 56, drawn to a method for detecting cancer associated with the presence of an antibody in a test serum sample comprising the step of detecting a level of **one or one combination** of antibodies against an antigen polypeptide selected from the group consisting of SEQ ID NOs: 8, 14, 16…1737, 1739 and 1741 or a fragment thereof, classified in class 435, subclass 2.

XI. Claims 57-60, drawn to an a method for screening for a bioactive agent capable of modulating the activity of **one** CA protein selected from the group consisting of the polypeptides encoded by SEQ ID NOs: 7, 13, 15…1736, 1738 and 1740; combining said protein and a candidate bioactive agent; and determining the effect of the agent on the bioactivity of the protein, classified in class 435, subclass 7.1.

XII. Claim 61, drawn to a method for diagnosing cancer comprising determining the level of expression of **one or one combination** an nucleic acid sequences selected from the group consisting of the human genomic and mRNA sequences outlined in Tables 1-152 in a first tissue type of a first individual and comparing said expression to that in a second normal tissue type from said first individual or a second unaffected individual, classified in class 435, subclass 6.

XIII. Claims 64-66, drawn to a method inhibiting expression of a cancer associated gene in a cell comprising contacting a cell expressing a CA gene with a double-stranded RNA comprising a sequence capable of hybridizing to one CA mRNA selected from the group consisting of SEQ ID NOs: 7, 13, 15…1736, 1738 and 1740, classified in class 435, subclass 375.

Groups I-XIII are comprised of multiple independent and/or distinct inventions recited in the alternative which are the products or methods drawn to different nucleic acids/polypeptides which do not render each other obvious and thus are patentably distinct. Applicant must elect a single invention which is the product or method drawn to one specific nucleic acid/polypeptide or one specification combination of nucleic acids/polypeptides to which the claims will be restricted. Applicant must also indicate which claims are readable on the elected invention. This is not an election of species because the nucleic acids/polypeptides are different and distinct and thus the methods drawn to different and distinct nucleic acids/polypeptides are different and distinct inventions

from each other. Note, this restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase in size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for reviewing the computer search results. Therefore, the limited resources of the Office no longer permit examination of more than one sequence in an application.

Note: the non-standard format of this restriction, separating the inventions into multi-invention groups drawn to independent or distinct types of products and methods, followed by an election of a single invention drawn to one sequence within the elected multi-invention group, was done for the sake of compactness of the communication and clarity, instead of using the more standard format setting forth each separate invention drawn to each separate sequence which would require a much longer communication.

Please note the new guidelines with regard to nucleotide sequence searches published as a pre-OG notice on March 27, 2007, and available at

http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/sequence02212007.pdf. This notice rescinds the 1996 OG Notice that provided for a partial waiver of the requirements for restriction practice by permitting examination of a reasonable number, up to ten, independent and distinct polynucleotide molecules in a single 35 USC 111(a) or 35 USC 371 application (see 1192 Off. Gaz. Pat. Office 68, No. 19, 1996).

The Office decision to rescind the 1996 waiver is based upon the increasing computational, search and examination burden required for the consideration of nucleic acid sequences, and complexity of claims drawn to such, compared to the time of the 1996 waiver (see the statistics cited in the pre-OG Notice at the link above).

Therefore, in accordance with 37 CFR 1.499, Applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Inventions I, II, III, IV and VII are directed to related products. The related inventions are distinct if (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope,

i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design and mode of operation. Each of the nucleic acids/vectors/host cells comprised in Group I have unique structures and sequences which impart distinct and different biochemical properties upon the products. Moreover, the nucleic acids/vectors/host cells of Group I are drawn to a single sequence which encodes a polypeptide, whereas the Group II microarray comprises a portion of a combination of nucleic acids, each with a structure and sequence which is distinct and different and which therefore has distinct and different biochemical properties. The polypeptides comprised within the Group III inventions are comprised of amino acids (not nucleotides as in the Group I and Group II inventions) and each polypeptide comprised within Group III also has a different and distinct sequence with different and distinct biochemical properties. The antibodies of Group IV, like the polypeptides of Group III are comprised of amino acid residues, but have a materially different design and mode of operation from the other products because they form antibodies which are capable of specifically binding to a particular polypeptide within the Group III invention. Furthermore, the antibodies each have a

different and distinct sequence which imparts a different and distinct biochemical property, e.g., specific recognition of an epitope. Finally, the electronic library of polypeptide sequences is comprised of a combination of polypeptides each of which are different and distinct and have different and distinct biochemical properties. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions V, VI, VIII, IX, X, XI, XII and XIII are directed to related processes. The related inventions are distinct if (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design and mode of operation. The Group V method comprises a method step wherein cancer cells are detected with an antibody; the Group VI method comprises the inhibition of cell growth with an antibody; the Group VIII method comprises a step of screening for anticancer activity utilizing one or one combination of nucleic acid(s); the Group

IX method comprises the step of detecting cancer by determining the level of expression of a polypeptide; the Group X method comprises the step of detecting cancer based upon the presence of a particular antibody in a test serum sample; the Group XI method comprises a step of screening a bioactive agent for its ability to modulate the activity of a polypeptide; the Group XII method comprises the method step of diagnosing cancer by determining the level of expression of one or one combination of nucleic acid sequences; and the Group XIII method comprises inhibiting expression of a cancer associated gene through the use of a double-stranded RNA. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I and VIII & XI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product of Group I can be used in either the inventions of Group VIII or the inventions of Group XI.

Inventions I and V, VI, IX, X, XII & XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the Group I nucleic acids/vectors/host cells are not disclosed as being capable of use with the inventions of Groups V, VI, IX, X, XII & XIII, and the inventions have a different design and mode of operation as explained above.

Inventions II and VIII, XI & XII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product of Group II can be used in either of the inventions of Group VIII, XI or XII.

Inventions II and V, VI, IX, X & XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the Group II microarray is not disclosed as being capable of use with the inventions of Groups V, VI, IX, X & XIII, and the inventions have a different design and mode of operation as explained above.

Inventions III and X & XI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product of Group III can be used in either the invention of Group X (as a positive control) or the invention of Group XI (to detect polypeptide binding to bioactive agents).

Inventions III and V, VI, VIII, IX, XII & XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the Group III polypeptide is not disclosed as being capable of use with the

inventions of Groups V, VI, VIII, IX, X, XI, XII & XIII, and the inventions have a different design and mode of operation as explained above.

Inventions IV and V, VI, IX, X & XI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibody of Group IV can be used in either of the Group V, VI, IX, X & XI processes.

Inventions IV and VIII, XII & XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the Group IV antibody is not disclosed as being capable of use with the inventions of Groups VIII, XII & XIII, and the inventions have a different design and mode of operation as explained above.

Inventions VII and IX & XI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the electronic protein library of Group VII can be used in the invention of Group IX or in the invention of Group XI.

Inventions VII and V, VI, VIII, X, XII & XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the Group VII electronic protein library is not disclosed as being capable of use with the inventions of Groups V, VI, VIII, X, XII & XIII, and the inventions have a different design and mode of operation as explained above.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there

would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view

the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Joseph Woitach can be reached at (571) 272-0739.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

June 10, 2007

DAVID GUZO
PRIMARY EXAMINER